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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

5/4

Office Action Summary

Application No.

09/855,604

Applicant(s)

GICQUEL ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 75-147 is/are pending in the application.
- 4a) Of the above claim(s) 87-99, 101-115 and 119-147 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 75-86, 100 and 116-118 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1 and 75-147 are pending. Claims 87-99, 101-115 and 119-147 have been withdrawn from consideration. Claims 1, 75-86, 100 and 116-118 are currently under consideration.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1, 75-86, 100 and 116-118 and SEQ ID NO:1 in the paper filed 17 July 2003 is acknowledged. The traversal is on the following grounds: (1) that no serious search burden exists because the search for Group I would encompass the search for the remaining groups and (2) that the commissioner has waived the requirements relating to restrictions relating to nucleotide or amino acid sequences. Applicant's arguments have been noted and not found persuasive for the reasons of record and those below. The search required for the present Group is not required for the other groups because products of one group is not required to produce the products of the other methods. Moreover, the other groups require the search of nucleic acid database, which are not required for the search of the present group; thus the searches are not coextensive in scope.

With regard to Applicant's argument that ten amino acid or nucleic acid sequences should be examined, the Commissioner's position states that "in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application." Applicant interprets this passage to mean that they are entitled to the search of ten sequences. The language states that Applicant may receive the search of at most ten sequences; and that restriction to fewer than ten independent and distinct nucleotide sequences is permissible. Additionally, based on the current sizes of the nucleic acid and amino acid databases and their

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exponential growth, a serious search burden exists in searching more than one sequence.

[A]pplicant may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions. See MPEP 803.04.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon applications filed in France, FR 97 10404 and FR 97 11325, on 14 August 1997 and 11 September 1997, respectively. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 75, 76 and 79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 6 of U.S. Patent No. 6,248,581. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 79 are generic to the expression vector recited in claims 5 and 6 of U.S. Patent No. 6,248,581. The expression vector of the prior patent is drawn to a recombinant vector comprising: (1) a replicon functional in mycobacteria; (2) a selectable marker; and (3) a reporter cassette comprising a polylinker, a nucleotide sequence comprising DNA or cDNA inserted into the polylinker, a transcription terminator upstream of the polylinker and a coding sequence derived from a gene encoding a marker or reporter for expression and/or export and/or secretion of protein lacking its initiation codon and regulatory sequences.

The vector of the present claims comprises a replicon functional in mycobacteria and a reporter cassette comprising: (a) a polylinker; (b) optionally a transcription terminator upstream of the polylinker; (c) a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, said nucleotide sequence lacking its initiation codon and its regulatory sequences, and (d) a coding nucleotide sequence for a marker. Both the present claims and the claims of the prior patent recite a cassette having a replicon, a polylinker, a transcription terminator, a coding sequence lacking its initiation codon and regulatory sequences

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and a marker. Moreover claim 6 of the patent recites the tT4 terminator which is also found in claim 79 of the present application and column 2, lines 9-20 of the patent supports the generic claims to the markers and discloses phoA, β -agarase, β -lactamase and nuclease of staphylococcus which are recited in claims 76 to 78 of the present application.

Claim Objections

Claims 116-118 are objected to because they are drawn to non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 75, 76, 79, 81-84 and 100 are rejected under 35 U.S.C. 102(b) as being anticipated by either Gicquel et al. (US 6,248,581 B1) ('581 Patent) or Gicquel et al. (WO 96/07745) (WO '745).

The invention of the present claims is drawn to a recombinant vector comprising a replicon functional in mycobacteria and a reporter cassette comprising: (a) a polylinker; (b) optionally a transcription terminator upstream of the polylinker; (c) a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, said nucleotide sequence lacking its initiation codon and its regulatory sequences, and

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(d) a coding nucleotide sequence for a marker. The claims are also drawn to the tT4 terminator, phoA, β -agarase, β -lactamase and nuclease of staphylococcus. The vector according to claim 81 is drawn to a vector wherein a polypeptide capable of export and/or of being secreted and/or being repressed or induced during an infection and/or of constitutive expression, e.g. phoA, is present in one site of the polylinker. The mycobacterium of the claims is *M. tuberculosis*, *M. africanum*, *M. bovis*, *M. avium* or *M. leprae*.

The '581 Patent discloses a recombinant vector comprising: (1) a replicon functional in mycobacteria; (2) a selectable marker; and (3) a reporter cassette comprising a polylinker, a nucleotide sequence comprising DNA or cDNA inserted into the polylinker, a transcription terminator, tT4, upstream of the polylinker and a coding sequence derived from a gene encoding a marker or reporter for expression and/or export and/or secretion of protein lacking its initiation codon and regulatory sequences, phoA. See claim 5 and 6, column 1, line 60 to column 2 line 25. See also WO '745 abstract and pages 2-3. The '581 Patent also discloses phoA, β -agarase, β -lactamase and nuclease of staphylococcus. The '581 Patent discloses *M. tuberculosis*, *M. africanum*, *M. bovis*, *M. avium* or *M. leprae*. See column 3, line 64. See also WO '745 page 5. In column 10 starting at line 40, the '581 Patent discloses pJEM11 has a truncated phoA without initiation codon or any regulatory elements inserted into a polylinker. See also WO '745 page 19.

Claims 1, 75-86, 100 and 116-118 are rejected under 35 U.S.C. 102(b) as being anticipated by Gicquel et al. (FR 2 767 336) ("FR '336").

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The invention is relied upon as described above. The present claims are additionally drawn to specific plasmids and transformed host cells.

FR '336 discloses a recombinant vector comprising a replicon functional in mycobacteria and a reporter cassette comprising: (a) a polylinker; (b) optionally a transcription terminator upstream of the polylinker; (c) a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, said nucleotide sequence lacking its initiation codon and its regulatory sequences, *phoA*, and (d) a coding nucleotide sequence for a marker. See abstract and pages 8, page 52 starting at line 29 to page 53. FR '336 also discloses *phoA*, β -agarase, β -lactamase and nuclease of staphylococcus in addition to luciferase and GFP. See page 53 line 18. FR '336 discloses a polypeptide capable of export and/or of being secreted and/or being repressed or induced during an infection and/or of constitutive expression, e.g. *phoA*, is inserted into the polylinker. See page 52, line 29 to page 53. The mycobacterium of the claims is *M. tuberculosis*, *M. africanum*, *M. bovis*, *M. avium* or *M. leprae*. See page 11, line 27. FR '336 also discloses the specific plasmids of the present claims. These plasmids disclosed by FR '336 include p6D7, p5A3, p5F6, p2A29, pDP428, p5B5, p1C7, p2D7, p1B7, pJVED/*M. tuberculosis*, pJVEDa, pJVEDb, pJVEDc. See figures 5 and 7-14 and see pages 9-11.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 75-86, 100 and 116-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The present claims are drawn to a "recombinant screening, cloning and/or expression vector." It is not clear what activity the vector claimed by applicant has? Is it used for each of these together or does can it function as any one type of these vectors alone. Therefore, the claims are inherently vague and indefinite.

Claim 81 recites a series of the term "and/or." This construction of the claim renders it unclear as to whether the all the clauses are limitations to the claim, some of the clauses are limitations to the claim or whether none are limitations to the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves



JAMES KETTER
PRIMARY EXAMINER